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10/734,381

12/12/2003

Robert Vincent Faller

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EXAMINER

KRASS, FREDERICK F

ART UNIT

PAPER NUMBER

1614

MAIL DATE

DELIVERY MODE

05/22/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/734,381

Applicant(s)

FALLER ET AL.

Examiner

Frederick Krass

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 04/30/07 (RCE Filing).
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) 7-9 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6 and 10 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- ☐ Notice of Informal Patent Application
- ☐ Other: \_\_\_\_\_.

### **Previous Rejections**

Unless specifically repeated/maintained infra, all previous rejections are withdrawn.

### **Anticipation Rejection**

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6 and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Degenhardt et al (USP 4,877,603).

Patentees disclose compositions comprising geminal diphosphonate polymers, and methods for inhibiting formation of calculus and plaque by treatment of the oral cavity therewith. Preferred polymers include acrylate/diphosphonate copolymers (column 9, lines 44-63); preferred additional active components include antiplaque agents such as chlorhexidine (column 17, lines 13-25) and fluoride anticaries agents in amounts of from 0.005 to 2 percent by weight (column 18, first paragraph; see also the working examples at columns 24 and 25, wherein the dentifrice compositions contain 0.25 percent sodium fluoride, which would be expected to provide approximately 250 ppm free fluoride). The inclusion of these fluoride compounds would provide “enhanced fluoride incorporation

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into and remineralization of the subject's teeth" as compared to the same formulation containing no fluoride.

The instant specification specifically states that the anticalculus agents disclosed in USP 4,877,603 are suitable for providing compositions having the requisite combination of properties necessary to provide increased hydrophilic character to teeth surfaces and extended surface conditioning effects which enhance protection of the teeth against caries, cavities and acid-induced demineralization. See page 6, lines 10-29. Moreover, the prior art specifically teaches that its polymers are substantive to teeth surfaces: see the passage bridging column 5, line 53 to column 6, line 8. Given these facts, it is clear that the prior art polymers inherently possess all the characteristics required by the instant claims.

#### **Discussion: Potentially Allowable Subject Matter**

The examiner has fully considered applicant's arguments, including allegations of unexpected results. The examiner does agree that an unexpected increase in the rate of fluoride uptake has been demonstrated for certain specific compositions, as shown by the comparisons made in the working examples of this application as originally filed.

Those showings are not persuasive of allowability for the claims in their current scope, however, because they are limited only to dentifrice compositions containing either 1) ITC 1087 (a diphosphonate/acrylate copolymer having an average molecular weight of 3,000 to 60,000) or 2) Polymer 1154 (a diphosphonate/acrylate copolymer

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having an average molecular weight of 6,000 to 55,000). See page 8, lines 5-7, and Tables 1-4 at page 19 of the instant specification.

The instant claims are much broader in scope, however, as reflected in their anticipation by the prior art. Anticipation cannot be overcome by showings of unexpected results. The claims could potentially be rendered allowable by limiting them to poly(diphosphonate/acrylates) having molecular weights in the range of 3,000 to 60,000. To do so it will be necessary, however, to identify the specific monomers used to produce the ITC 1087 and Polymer 1154 products, in order that a proper evaluation of the probative value of the unexpected results could be conducted.

#### **Provisional Nonstatutory (“Obviousness-Type”) Double Patenting Rejection**

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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Claims 1-6 and 10 were rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4 of U.S.S.N. 10/737,425 in view of Gaffar et al (USP 5,032,386).

This is a provisional rejection since the copending claims have not yet been patented in fact.

This rejection is maintained, pending submission of the Terminal Disclaimer promised by Applicant.

### **Correspondence**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frederick Krass whose telephone number is (571) 272-0580. The examiner can normally be reached at (571) 272-0580 on Monday through Friday from 9:30AM to 6:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, can be reached at (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you

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have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Frederick Krass  
Primary Examiner  
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A handwritten signature in black ink, appearing to read 'Fred Krass', written in a cursive style.